

Amendment and Response
Serial No.: 10/729,114
Confirmation No.: 3162
Filed: 5 December 2003
For: WOUND DRESSINGS AND METHODS

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Remarks

The Office Action mailed December 15, 2008 has been received and reviewed. Claims 1, 19, 20, 26, and 28 having been amended, claim 4 having been cancelled, without prejudice, the pending claims are claims 1-3 and 5-20. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejection

Claims 1-28 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of copending U.S. application no. 10/728,577. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 26 and 28 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner objected to a wound dressing "swollen with liquid" but acknowledged the fact that the specification provides written description for a swollen wound dressing. It is not clear why it would not be understood to one of skill in the art that a liquid would cause the swelling, particularly in view of the specification at page 4, lines 18-24; however, in the interest of expediting prosecution, these claims have been amended. Withdrawal of this rejection is requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-8, 13-18, 21 and 24-28 under 35 U.S.C. §103 as being unpatentable over WO 2002/066087 (COLOPLAST A/S). The Examiner rejected claims 9-11, 19, 20, 22, and 23 under 35 U.S.C. §103 as being unpatentable over WO 2002/066087

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(COLOPLAST A/S) in view of "SALCARE[®] SC95" by Ciba[®]. The Examiner rejected claim 12 under 35 U.S.C. §103 as being unpatentable over WO 2002/066087 (COLOPLAST A/S) in view of Brook (U.S. Patent No. 4,902,565). These rejections are traversed.

There is no teaching or suggestion in WO 02/066087 to make a nonadherent polymer composition. WO 02/066087 is drawn specifically to an adhesive composition. It is respectfully submitted that although a definition per se may not be provided in WO 02/066087, one of skill in the art would clearly understand that the compositions of WO 02/066087 are adhesives that "must provide sufficient adhesive strength to adhere the microcolloid containing composition of the invention to the skin of the user" (page 17, paragraph 1).

Contrary to the Examiner's assertion, simply starting with an adhesive composition and modifying it to be nonadhesive is not a routine matter. Adhesive compositions are complex compositions and are not necessarily simply made nonadhesive by taking something out. They can be made nonadhesive by modifying the types of components, the amounts of components, adding components, etc.

At page 11 of the Office Action, the Examiner stated "one having ordinary skill in the art would have prepared the polymer composition disclosed by WO '087, and eliminate the adhesive if not desired" (emphasis added). This implies that the "adhesive" is an element or component of the composition. This is not necessarily the case. In the present case, the "adhesive" is a property of the composition – not a component of the composition that can be merely "taken out." The adhesive property results from the types and amounts of components – not from any one particular "adhesive component."

In reality, one of skill in the art looking for a nonadhesive composition does not necessarily start with an adhesive composition and modify it to be nonadhesive. This is because varying the amounts and types of the components of an adhesive composition can, and typically will, adversely impact other properties of the composition. So, it is not a trivial matter to remove the "adhesive property" of an adhesive composition without changing other properties.

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Furthermore, if one were looking at WO 02/066087 to determine how one would remove the "adhesive property" of the adhesive composition described therein, one would be led down a road to use different particles than are claimed by Applicants (it is noted that each of Applicants' claims recites hydrophilic organic microparticles that, when in a nonhydrated form, have an average particle size of 10 microns or less). Specifically, WO 02/066087 provides data that demonstrates the compositions of WO 02/066087 have reduced adhesion if particles having larger particle size are incorporated therein. The Examiner's attention is directed to Tables 2 and 5 of WO 02/066087. Reduced adhesion occurs with AQUASORB A500, which is used in Adhesive A2 (Hydrocolloid Control). This material, as demonstrated by Exhibit A, has a particle size range of 75 to 250 microns, as opposed to the microcolloid used in Adhesive A1, which has a particle size range of 0.5 to 1 micron (see, e.g., page 21 of WO 02/066087, line 3 under heading "Example 2"). Thus, making a composition using the recited hydrophilic organic microparticles (which when in a nonhydrated form have an average particle size of 10 microns or less) is contrary to the specific teachings of WO 02/066087. As a result, WO 02/066087 teaches away from making a nonadhesive composition that includes organic microparticles, which when in a nonhydrated form have an average particle size of 10 microns or less.

Therefore, removal of the rejection based on WO 2002/066087 (COLOPLAST A/S) is respectfully requested. With respect to claims 9-11, 12, 19, 20, 22, and 23, and "SALCARE[®] SC95" by Ciba[®] and Brook (U.S. Patent No. 4,902,565), these documents do not add that which is missing from WO 2002/066087. Withdrawal of all the rejections presented herein is requested.

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Summary

It is respectfully submitted that the pending claims 1-3 and 5-20 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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April 9, 2009
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9th day of April, 2009, at 2:45pm (Central Time).

By:

Name:

Sam S. W. W. W. W.
Sam S. W. W. W. W.

Exhibit A

RECEIVED
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HERCULES

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Product Data

NUMBER 4221

AQUASORB® Sodium Carboxymethylcellulose For Superabsorbent Applications

AQUASORB® sodium carboxymethylcellulose is a high purity, powdered superabsorbent. It is used in food, medical, personal care and many other products, that require high absorbency of aqueous fluids.

All analytical methods given below are available upon request.

Types and Specifications

Specifications	A380	A500	Method of Analysis
Purity on dry basis	99,5% min.	99,5% min	
Moisture, as packed	8% max.	6% max	
pH	6,5-8,0	6,5-8,0	MA 304.1004A
Product colour	white to light tan	white to light tan	
Absorbency of the product as is:			
- in a sanitary napkin after 30 minutes immersion	22 g/g (1% NaCl/g)	—	MA 304.1400A
- with tea-bag test after 10 minutes	—	30 g/g min. (1% NaCl/g)	MA 304.1402A
Particle size distribution, sieve opening			MA 304.1602A
	1% max. on 0,850 mm	0,5% max. on 0,250 mm	
	10% max. thru 0,180 mm	80% min. thru 0,075 mm	

Depending upon their technical and commercial feasibility, special grades to meet individual customer requirements can be made available. Please consult with our sales force.

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Properties and Uses

Aquasorb® does not contain any cross-linking agent. Due to its chemical similarity to sodium carboxymethylcellulose Aquasorb is expected to be physiologically inert. The product is neither a primary irritant nor a sensitizing agent. Recommended applications are:

Aquasorb A380

- Feminine hygiene sanitary napkins
- Baby diapers
- Adult incontinence pads or diapers
- Wound dressings and ostomy products
- Meat packaging

Aquasorb A500

- Wound dressings and ostomy products
- Bakery products, to control water content in dough to improve shelf life and to increase volume.

Regulatory Status

Aquasorb complies with the purity specifications for sodium carboxymethylcellulose as laid down in the current edition of the European Pharmacopoeia (EP) and in the United States Pharmacopoeia (USP). Aquasorb is produced in Alizay, France. This facility complies with Current Good Manufacturing Practice Regulations (CGMPRs) as specified in the U.S. Code of Federal Regulations.

An ADI (acceptable daily intake) of "not specified" has been allocated to modified cellulose by the Scientific Committee for Food of the Commission of the European Community, and by the Joint FAO/WHO Expert Committee on Food Additives. The European Commission has also assigned to CMC the number E-466 to designate its food approval status in the Community. Almost all countries in Europe and in the world permit the use of sodium carboxymethylcellulose in food.

Packaging and Storage

Aquasorb is packed in 3-ply paper bags of 25 kg, with removable polyethylene inner bag. These are supplied on pallets of 40 bags each.

Aquasorb is a non-perishable powder. It is recommended to use the product in rotation on a first-in first-out basis. The product should be stored under dry and clean conditions in its original packing and away from heat. The product is hygroscopic. The packaging is selected in a way to avoid ingress of moisture, but the water content of the packed product will/may increase if not stored dry.

Product Safety

According to the EC legislation on dangerous substances and preparations these products are not hazardous. Further data on the safety aspects of Aquasorb are available from Safety Data Sheet 21.489.

Toxic Substances Information

CAS Number: (9004-32-4)

CAS Name: Cellulose, Carboxymethyl ether, Sodium Salt

4-02

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